



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2020-0050; FRL-8560-01-OCSP]

#### Boscalid; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of boscalid in or on tea, dried; tea, instant. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2020-0050, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information

on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDFRNotices@epa.gov](mailto:RDFRNotices@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

#### *C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID

number EPA-HQ-OPP-2020-0050 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2020-0050, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the *Federal Register* of September 30, 2020 (85 FR 61681) (FRL-10014-74), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E8819) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.589 be amended by establishing tolerances for residues of the fungicide boscalid in or on tea at 80 parts

per million (ppm). That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. No comments were received in response to the notice of filing.

FFDCA section 408(d)(4)(A)(i) permits the Agency to finalize a tolerance that varies from that sought by the petition. Based upon review of the data supporting the petition, EPA has modified the tolerance level being established and corrected the commodity definition of “tea” to “tea, dried” and “tea, instant.” The reason for these changes is explained in Unit IV.D.

### **III. Aggregate Risk Assessment and Determination of Safety**

#### *A. Statutory Background*

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D) and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for boscalid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with boscalid follows.

#### *B. Aggregate Risk Assessment*

In an effort to streamline *Federal Register* publications, EPA is not reprinting sections

that have not changed from previous rulemakings for the same pesticide. On October 19, 2018, EPA published in the *Federal Register* a final rule establishing tolerances for residues of boscalid in or on multiple commodities based on the Agency's conclusion that aggregate exposure to boscalid is safe for the general population, including infants and children. *See* 83 FR 52991 (EPA-HQ-OPP-2017-0310). Refer to the following sections from the previous tolerance rulemaking for boscalid that have remained the same under the current risk assessment: Units III.A (Toxicological Profile); III.B (Toxicological Points of Departure/Levels of Concern); III.C. (Exposure Assessment), except as explained below; and III.D. (Safety Factor for Infants and Children). EPA has conducted an updated human health risk assessment to evaluate the safety of the requested tolerances, which is limited to an updated dietary exposure and risk assessment, and subsequent updates to the aggregate exposure and risk assessment. *See* "Boscalid. Human Health Risk Assessment for the Establishment of a Permanent Tolerance Without a U.S. Registration on Tea." (D456100, 04/01/2021), which is available in the docket established by this action, EPA-HQ-OPP-2020-0050.

Updates to exposure assessment. EPA's dietary (food and drinking water) exposure assessments have been updated to include the potential additional exposure from the tolerance for boscalid residues in or on tea, dried and tea, instant. The exposure assessments relied on tolerance-level residues for all crops and an assumption of 100 percent crop treated (PCT) as the October 19, 2018, final rule. Exposure in drinking water and from residential sources are not impacted by the increased tolerance on tea, dried and tea, instant because the tolerances are without U.S. registration.

*Assessment of aggregate risks.* An acute dietary exposure assessment was not conducted because there were no observed effects attributable to a single dose. Chronic dietary risks are below the Agency's level of concern of 100% of the chronic population adjusted dose (cPAD): 60% of the cPAD for children 1 to 2 years old, the most highly exposed population subgroup.

For the aggregate risk assessment, exposures to boscalid in food and drinking water are

combined with residential exposures for the relevant exposure duration period. There is potential for short-term aggregate exposure to boscalid via dietary (which is considered background exposure) and residential (which is considered primary) exposure pathways. The short-term aggregate margins of exposure (MOEs) are 160 for children 6 to 11 years old, 360 for youth 11 to 16 years old, and 130 for adults (LOC = 100), which are not of concern because they exceed EPA's level of concern (MOEs less than or equal to 100).

A separate cancer dietary assessment was not conducted since boscalid was classified by the Cancer Assessment Review Committee (CARC) as "suggestive evidence of carcinogenicity"; and the chronic exposure assessment is protective of any cancer risks. Therefore, based on the chronic exposure assessment, which accounts for potential carcinogenicity, EPA does not expect boscalid to pose a cancer risk.

### *C. Determination of Safety*

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to boscalid residues. More detailed information about the Agency's analysis can be found in the document entitled, "Boscalid. Human Health Risk Assessment for the Establishment of a Permanent Tolerance Without a U.S. Registration on Tea." (D456100, 04/01/2021) by going to <http://www.regulations.gov>.

## **IV. Other Considerations**

### *A. Analytical Enforcement Methodology*

Adequate methods exist for both plants and livestock. In plants, the parent residue is extracted using an aqueous organic solvent mixture followed by liquid/liquid partitioning and a column clean up. Quantitation is by gas chromatography using mass spectrometry (GC/MS) or liquid chromatography in tandem with mass spectrometric detection (LC/MS/MS). In livestock, the residues are extracted with methanol. The extract is treated with enzymes in order to release the conjugated glucuronic acid metabolite. The residues are then isolated by liquid/liquid

partition followed by column chromatography. The hydroxylated metabolite is acetylated followed by a column clean-up. The parent and acetylated metabolite are quantitated by gas chromatography with electron capture detection.

Adequate enforcement methodology, extraction using an aqueous organic solvent mixture followed by liquid/liquid partitioning and a column clean up with quantitation by gas chromatography using mass spectrometry (GC/MS) or liquid chromatography in tandem with mass spectrometric detection (LC/MS/MS), is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

#### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCa section 408(b)(4). EPA may establish a tolerance that is different from a Codex MRL; however, FFDCa section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for boscalid. Taiwan has an MRL for residues of boscalid in/on dried tea leaves at 10 ppm, and Japan has an MRL of residues of boscalid in/on dried tea leaves at 60 ppm. The tolerance expression for Taiwan and Japan are harmonized with the US tolerance definition in crops as parent boscalid only but do not metabolites and degradates. All international MRLs fall below the calculated tolerance value of 70 ppm.

#### *C. Revisions to Petitioned-For Tolerances*

The petitioned-for tolerance for residues on the commodity tea at 80 ppm is revised so that there will be two separate tolerances for residues on tea, dried and tea, instant each at 70 ppm and corrected commodity definitions. The tolerance is also revised pursuant to a difference

in how the tolerances are calculated. The registrant calculated a processing factor for dried black tea as 4.1x and used the field trial values from the fresh leaves at 7-days. EPA determined the processing factor to be no greater than 2.54x and extrapolated the 7-day residues for black tea based on the combination of the processing factor and the decline trend for fresh leaves.

## **V. Conclusion**

Therefore, tolerances are established for residues of boscalid, in or on Tea, dried; and Tea, instant at 70 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and



responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

## **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 2, 2021.

**Marietta Echeverria,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

**PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.589 amend the table in paragraph (a)(1) by adding in alphabetical order entries for “Tea, dried<sup>2</sup>” and “Tea, instant<sup>2</sup>” to read as follows:

**§ 180.589 Boscalid; tolerances for residues.**

(a) \* \* \*

(1) \* \* \*

Commodity	Parts per million
* * * * *	* *
Tea, dried <sup>2</sup>	70
Tea, instant <sup>2</sup>	70
* * * * *	* *

<sup>2</sup>There are no U.S. registrations for these commodities as of [INSERT DATE OF PUBLICATION IN *FEDERAL REGISTER*].

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[FR Doc. 2021-16973 Filed: 8/12/2021 8:45 am; Publication Date: 8/13/2021]